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JEFFREY J. KING, ESQ
GRAYBEAL JACKSON HALEY LLP
155- 108 TH AVENUE, N.E., SUITE 350
BELLEVUE, WA 98004-5901

EXAMINER
LUCAS, ZACHARIAH

ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/444,221	Applicant(s) MURPHY ET AL.	
	Examin r Zachariah Lucas	Art Unit 1648	

-- The MAILING DATE of this communication app ars on the cov r sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *63-76 and 90-145* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *63,90,93,94,100,101,103,114-124,127,131 and 133* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Continuation of Disposition of Claims: Claims withdrawn from consideration are 64-76,91,92,95-99,102,104-113,125,126,128-130,132 and 134-145.

DETAILED ACTION

Status of the Claims

1. Currently, claims 63-76 and 90-145 are pending in the application. Claims 64-76, 91, 92, 95-99, 102, 104-113, 125, 126, 128-130, 132, and 134-145 are withdrawn as to non-elected inventions. Claims 63, 90, 93, 94, 100, 101, 103, 114-124, 127, 131, and 133 are pending and under consideration. A Final rejection was issued against these claims on June 26, 2003 (the prior rejection). On June 20, 2003, the Applicant submitted a Request for Continued Examination (RCE). In a Response filed with the RCE, the Applicant amended claims 117, and 122-124, and cancelled non-elected claims 77-89, 146, and 147.

2. The Art Unit location of your application, and the examiner to whom the case has been docketed in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Zachariah Lucas in Art Unit 1648.

Specification

3. **(New Objection)** The disclosure is objected to because of the following informalities: the reference to the virus RSV B-1-cp-23 in the application is not accompanied by the virus' ATCC deposit number. It is suggested that the application be amended such that on page 7, line 5, the parenthetical -- (ATCC VR 2579)-- be inserted after the term "B-1 cp-23."

Appropriate correction is required.

4. **(New Objection)** The disclosure is objected to because of the following informalities: on page 7 of the application, the description identifies the ATCC as being in Rockville Maryland. However, as noted in the Official Gazette (1210 OG 74, May 26, 1998), the address of the ATCC has changed to:

American Type Culture Collection (ATCC)
10801 University Blvd.
Manassas, Va. 20110-2209
USA.

In the OG, it was also noted that patent applications pending before the Office are requested to amend the specification to change the ATCC address as indicated.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. **(New Rejection)** Claims 63, 90, 100, 101, 103, 115-124, 127, 131, and 133 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 63 is being treated as representative. This claim reads on isolated infectious recombinant respiratory syncytial virus (RSV) comprising a genome or antigenome, and a major nucleocapsid (N) protein, a nucleocapsid phosphoprotein (P), a large polymerase protein (L), and a RNA polymerase protein, wherein the genome or antigenome comprises "a deletion, insertion,

rearrangement, or nucleotide modification of a cis-acting regulatory sequence within the recombinant RSV genome or antigenome." The claims are rejected because it is unclear whether the genome or antigenome comprises a deletion, insertion, substitution, or rearrangement anywhere within the genome, or a nucleotide modification within a cis-acting regulatory sequence, or if the all of the claimed types of genome modifications are to be found in the regulatory sequence.

From a reading of the specification in combination with the claim language, it appears as thought the nucleotide modification of the regulatory sequences is in alternative to the other modifications to the genome or antigenome generally. This is because the application does not appear to recognize any modifications other than deletions, insertions, rearrangements, or substitutions. See e.g., App., page 30, lines 8-18 (identifying the modifications that may be used to achieve the desired pheno- or genotypical changes). It is suggested that the claim be amended to state --wherein a modification is introduced within a cis-acting regulatory sequence of the genome or antigenome, said modification comprising a deletion, insertion, substitution, or rearrangement.--

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. **(Prior Rejection- Maintained)** Claim 101 was rejected in the prior action under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The basis of

this rejection is that the Applicant has not met the requirements for making a Deposit. While the Applicant has made reference to the ATCC deposits in the body of the Application, the Applicant has not made the assurance of compliance with the deposit rules. The Applicant's submission of a Declaration intending to perform this function is noted. However, this declaration is not effective in that it contains a handwritten correction on page 2 of the declaration that is neither initialed, nor dated, as required by 37 CFR 1.52(c). Thus, the Declaration is not effective, at least for the contents of the Declaration relating to the virus of ATCC 2542. In view of the above, the rejection is maintained.

9. **(Prior Rejection- Withdrawn)** Claims 117-124 were rejected in the prior action under 35 U.S.C. § 112, first paragraph, for lack of enablement. The claims have been amended such that they no longer read on embodiments wherein the viral compositions must induce a protective response in an individual, or on vaccine compositions. In view of the amendments, and the arguments made pursuant thereto, this rejection is withdrawn.

10. **(New Rejection)** Claims 63, 90, 93, 94, 100, 101, 103, 114-124, 131, and 133 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims read on embodiments of the claimed chimeric RSV wherein the virus comprises a RNA polymerase elongation protein. Thus, the claim as written encompasses a generic class of chimeric RSV virus, each of which may contain any RNA polymerase

elongation factor. The specification does not provide adequate written description support for the full scope of these generic claims.

The following quotation from section 2163 of the Manual of Patent Examination Procedure is a brief discussion of what is required in a specification to satisfy the 35 U.S.C. 112 written description requirement for a generic claim covering several distinct inventions:

> The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice..., reduction to drawings..., or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus... See Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406.
>
> A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

Thus, when a claim covers a genus of inventions the specification must provide written description support for the entire scope of the genus. Support for a genus is generally found where the applicant has provided a number of examples sufficient so that one in the art would recognize from the specification the scope of what is being claimed.

In the present case, the applicant has disclosed only a single example of a RNA polymerase elongation factor- the M2 ORF 1 protein of RSV. See e.g., page 7, lines 14-15; and pages 52-53, and 54, lines 1-7. Although the specification states that a "substantially equivalent transcription elongation factor" may be used instead of the M2 ORF1, neither the description nor the examples in the application provide any indication of what such substantially equivalent factors may be. Without examples, or some identification of the M2 ORF1 structure that is necessary to its operation, one in the art wishing to practice the invention has no indication as to what other proteins may be used in the claimed virus. In view of the lack of description for any

RNA polymerase elongation factor other than the M2 ORF1, the claims are rejected for exceeding the scope of descriptive support provided by the specification.

11. **(New Rejection)** Claims 63, 90, 93, 94, 100, 101, 103, 114-124, 131, and 133 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated infectious chimeric RSV wherein the virus comprises the M2 (ORF1) RNA polymerase elongation factor, does not reasonably provide enablement for viruses containing any RNA polymerase elongation factor. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

A claim is commensurate in scope with the enablement when the applicant has provided sufficient disclosure to enable one skilled in the art to practice the claimed invention without undue experimentation. In re Wands, 8 USPQ2d 1400, 1404 (CAFC 1988). There must be a "reasonable correlation" between the scope of enablement and the scope of the claims. In re Fisher, 166 U.S.P.Q. 18, 24 (CCPA 1970). Such correlation requires "sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and how to use the invention as broadly as it is claimed. This means that the disclosure must adequately guide the art worker to determine, without undue experimentation, which species among all those encompassed by the claimed genus possess the disclosed utility." See, In re Vaeck, 20 U.S.P.Q.2d 1438, 1444 (CAFC 1991) No such guidance is provided in the present case.

Both the present application (pages 52-53), and the art relevant to the claimed invention (see, Collins et al. PNAS 92:11563-11567- made of record in the IDS filed July 27, 2000), indicates that the M2 ORF1 protein is one of the minimal proteins necessary for an infectious RSV. Although the application does state that substantial equivalents of this identified protein may be used (page 63, lines 35-38), it does not identify any characteristic or examples which one of ordinary skill in the art could use as guides to identify such equivalents. Further, the combined teachings of the specification, indicating that only substantial equivalents of the M2 ORF1 protein may be used, and the art, teaching that an operative M2 ORF1 protein is necessary for an operative chimeric RSV (Collins et al., PNAS 92:11563-11567), indicate that only a specific subclass of RNA polymerase elongation factors may be used in the invention. As the application has provides no examples or other indication as to what proteins fall within this subclass, other than the M2 ORF1 protein itself, the application has not provided an enabling disclosure corresponding to the full scope of the rejected claims.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. **(New Rejection)** Claims 63, 115 is rejected under 35 U.S.C. 102(b) as being anticipated by Collins et al. (PNAS 92: 11563-67). The claims have been described above. For the purposes

of this rejection, the claim is being interpreted as reading on RSV particles that comprise any "deletion, insertion, substitution, or rearrangement" as an alternative to such nucleotide modifications limited to mutations within cis-acting regulator sequences. The Collins reference teaches isolates infections RSV particles comprising the N, P, L, and M2-1 (an RNA polymerase), and an RSV genome. Pages 11563-64. The reference also indicates that the genome has been modified to include at least one substitution (five), and one insertion. Page 11564, right column, first full paragraph. Thus, the reference anticipates the identified claims.

14. **(New Rejection)** Claims 63, 90, 100, 101, 103, 114, and 116-124 are rejected under 35 U.S.C. 102(b) as being anticipated by Crowe et al., Vaccine 12(9): 783-790. These claims read on RSV viral particles comprising a mutation in a cis-acting regulatory sequence, and an additional attenuating mutation, immunogenic compositions thereof, and on methods of inducing immune response with the viral particles. In the specification of the present application, on page 6 (lines 19-30), the Applicant discloses that the virus identified by the Crowe reference as RSV cpts-248/404 comprises a mutation in the M2 start sequence. Although the reference does not disclose that the virus has such a mutation, by the Applicant's admission, the virus disclosed by the reference meets the limitations of claim 63. Crowe further identifies this strain as also having cold-passaged and temperature sensitive mutations. Thus, the viral particle has at least two attenuating mutations, at least one of which is in a cis-acting regulatory sequence. Further, the reference describes the dosage and administration of the particles to Chimpanzees. Page 785. The compositions so administered meet the limitations of the present application. Thus, the reference anticipates the identified claims.

It is noted that the Crowe reference teaches that this mutant virus has significantly greater attenuation than its attenuated parent strain. Abstract. Further, the Collins reference teaches that the M2 gene encodes a protein necessary for viral replication. Abstract (disclosing the polymerase elongation activity of the M2-1 protein). From these two facts, it is reasonable to assume that the mutation in the M2 start gene had some effect on the expression of the M2-1 protein, thereby causing the increases level of attenuation. Thus, the reference also appears to anticipate claim 90, which requires that the RSV comprise a mutation that modulates the expression of a selected gene.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. **(Prior Rejections- Maintained)** Claims 63, 93, 94, 114, 115, 117, 121, 122-124, 127, 131, and 133 were rejected in the prior action under 35 U.S.C. 103(a) as being unpatentable over Collins et al. (PNAS 92: 11563-67) in view of any of Marr et al. (Virology 180(1): 400-05), Chen et al. (J Virol 67(3): 1218-26), or Doyle et al. (J Cell Biol 103(4): 1193-1204). The Applicant traverses this rejection on the basis that the Collins reference forms an inadequate basis on to support the rejections of record.

Specifically, the Applicant contends that there is no practical motivation to combine the teachings of Collins with those of the other references. The Applicant argues that the "the Collins et al. reference does not show successful recovery of a recombinant RSV having any genome modification as claimed. Moreover, the reference fails to establish that a recombinant RSV having a genome modification as claimed would be expected to possess such critical properties as replication competence, infectivity, immunogenicity, and attenuation *in vivo*" (emphasis in original). From this, the Applicant concludes that there is no practical motivation to combine the Collins reference with the other references to achieve the claimed invention.

With respect to the Applicant's first observation, that the Collins reference does not teach successful recovery of the claimed RSV particles, the Examiner would like to first point out that this is an obviousness rejection under 35 U.S.C. 103. In such rejections, it is established law that "One cannot show nonobviousness by attacking references individually." See, MPEP § 2145 IV (citing In re Keller, 208 U.S.P.Q. 871 (CCPA 1981), and In re Merck & Co., Inc., 231 U.S.P.Q. 375 (Fed. Cir. 1986)). Thus, the failure of Collins to teach recovery of particles with all of the claimed properties is not, without more, persuasive in traversing this rejection. Collins teaches how to make recombinant infectious RSV particles, and suggests the making of such particles wherein mutations are made to the virus that ablate or reduce the expression of the viral proteins. The other references teach that those in the art know that one way of ablating or reducing expression of the proteins is through alteration of the regulatory sequences. One skilled in the art would have been confident in the making of such particles, although the effect of the mutation may not have been known.

The Applicants second assertion, that neither Collins, nor the other references, teach that the claimed particles "possess such critical properties as replication competence, infectivity, immunogenicity, and attenuation *in vivo*" is both partially inaccurate, and partially irrelevant to the claimed invention. The Collins reference teaches that the viral particles achieved through the method taught therein results in infectious particles- one of the "critical properties." With respect to the remaining "critical properties," with the exception of immunogenicity, because the Collins reference teaches the minimum proteins required for viral replication (the N, P, L, and M2-1 proteins) and teaches that such particles are infectious, the reference does teach particles with the "critical properties" of the claimed inventions. With respect to the property of attenuation, the reference teaches the incorporation of several of the same attenuating modifications described in the present application. This feature is therefore accounted for.

It is noted that Collins does not specifically disclose the particles disclosed therein as being immunogenic. As indicated by the Applicant, immunogenicity is, with respect to certain of the claims, a required feature. However, immunogenicity, and the claims, requires only that the particles be capable of eliciting an immune response. As any foreign protein injected into an individual will achieve some immune response. Further, it is known that the RSV N and P proteins induce are antibody targets in individuals infected by the virus. See e.g., Jankowski et al., Res Virol 141(3): 343-53 (esp. abstract, indicating that antibodies against these two proteins were found in babies infected by RSV). Thus, immunogenicity would appear to be inherent to the Collins particles, and to the RSV virus, because they comprise both the N and P proteins.

As described in the prior action, Collins specifically teaches that the viral particles described therein could by used to investigate the functions of the viral proteins through

"introducing mutations that ablate or reduce their level of expression." Page 11566. Further, the reference also indicates that, among other attenuating mutations that may be found, one possibility is in the cis-acting signals of the virus. Page 11567. Thus, the reference explicitly suggests the making of the described viral particles with the indicated mutations. From this, those in the art would have been lead to make mutations (such as those in Marr, Chen, and Doyle) that achieve the indicated protein ablation or reduced expression. Thus, the references both teach and suggest the making of the claimed viral particles.

Further, as demonstrated by the Doyle and Chen references, the effects of the mutations may be studies through infection of cells or animals with the viral particles. Such infection would first require that the virus be isolated in some composition that could be introduced to the animals or cells. Such compositions would of necessity fall within the claimed genus of "immunogenic compositions."

17. **(Prior Rejection-Maintained)** Claims 90, 100, 101, and 103 were rejected over the above references, further in view of any of Crowe et al. (Vaccine 12(8): 691-99), Crowe et al. (Vaccine 12(9): 783-90), Crowe et al. (Vaccine 13(9): 847-55), or Murphy et al. (WO 93/21310). These claims read on the recombinant RSV described above, further comprising additional attenuating mutations. The Applicant traverses the rejection by arguing that it would be speculative to have incorporated cis-acting sequence mutations with other attenuating mutations. However, on page 11566, the Collins reference suggests the making of RSV particles comprising multiple attenuating mutations in the genome. Further, the reference also teaches that among possible other attenuating mutations that may be made are mutations of the cis-acting signals.

Page 11567. This suggestion is supported by the teachings of Clarke et al. (U.S. Patent 5,840,520), which also teaches the modification of regulatory sequence in the RSV genome to make attenuated virus. See e.g., col. 44, lines 19-31. Because the Collins reference and the art suggest the attenuation of RSV through modification of the regulatory sequences, and Collins teaches the combination of various attenuating mutations, the reference renders obvious to combination of such cis-acting mutations with other attenuating mutations. Thus, the Applicant's arguments that the references do not provide adequate motivation for the described combination are not found persuasive.

18. **(Prior Rejection-Maintained)** Claims 116, 118-120, 123, and 124 were rejected over Collins in view of any of Marr, Chen, or Doyle, further in view of Randolph et al. (EP 0 567 100). These claims identify effective dosages of the claimed viral particles. The Applicant traverses this rejection on the basis that the Randolph reference does not cure the defects of the primary references, and that Randolph's teachings regarding dosages and administration routes would be speculative at best. As indicated above, the Examiner is not persuaded that the Collins reference is as defective a primary reference as argued by the Applicant. Further, given the discussion above relating to the immunogenicity and the testing of the viral particles suggested by Collins, and the fact that the disclosures of both Collins and Randolph relate to the administration of mutant RSV particles for such evaluation, the teachings of Randolph regarding methods of such administration do not appear speculative. See e.g., Randolph, pages 17-18 (teaching administration of the experimental attenuated viruses to animals to determine their

immunogenic and vaccine efficacy). Rather, Randolph would appear to be teaching methods of administering virus in a manner directly applicable to the teachings of Collins.

19. **(New Rejection)** Claims 115, 127, and 131 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crowe as applied to claims 63, 90, 100, 101, 103, 114, and 116-124 above, and further in view of Collins. Claim 115 describes a viral particle according to claim 63 wherein the particle is a sub-virus particle. Claims 127 and 131 describe isolated polynucleotides comprising an RSV genome with a mutation in a cis-acting regulatory sequence. The teachings of Crowe are disclosed above. Collins teaches a method of introducing defined changes into an RSV genome. Further, the reference teaches the identification of mutations in known viruses, including the Crowe virus, so that the mutations can be inserted into viral genomes to "fine-tune" the viral attenuations. (See, page 11566, referring to reference 20 as a known attenuated virus, and suggesting the insertion of these mutations into wild-type virus to identify effective mutations). Such a process would require the isolation of the RSV genome such that it could be studied. Thus, the reference suggests the isolation of a genome that meets the limitations of claims 127-131.

Further, the Collins reference also teaches the combination of various attenuating mutations. Supra. Because the Crowe virus is disclosed as attenuated, it would have been obvious to those in the art to add further mutations to this viral genome. As Collins teaches method for making such mutants that results in a sub-viral particle, the reference renders claim 115 obvious, as it would have been obvious to one of ordinary skill in the art to further mutate the Crowe RSV for "fine tuning." Thus, the references render the claimed invention obvious.

Double Patenting

20. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

21. **(New Rejection)** Claims 63, 90, 100, 101, 103, 114-116, 122-124, 127, 131 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 5,993,824. Although the conflicting claims are not identical, they are not patentably distinct from each other because the presently identified claims are either generic to, or overlapping with, the claims of the identified patent. The rejected claims have been described above. The claims of the patent describe isolated RSV particles comprising "at least two attenuating mutations," including embodiments wherein the mutation is in the gene-start sequence of the M2 gene, and embodiments wherein the viral particle is RSV cpts 248/404 (identified as ATCC VR 2452 in claim 11 the patent, and as ATCC VR 2454 of the present application). Because this virus particle itself anticipates the identified claims as described above in the rejection over Crowe (Vaccine 12(9): 783-790), the claims of the patent are at least overlapping with the claims in the present application.

Conclusion

22. No claims are allowed.

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 703-308-4240. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Z. Lucas
Patent Examiner

JAMES HOUSEL 8/24/03
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600